REMARKS

The Official Action of January 5, 2010 constitutes a first Official Action containing a final rejection. Favorable action on the merits is solicited in view of the foregoing amendments and the following remarks.

I. Interview, Claim Status and Amendments

Applicants thank Examiner Swope for her time and consideration during the telephone interviews with the undersigned, the last of which was on July 1, 2010. See below for a summary of the interviews.

Claims 20, 25, 69, 70, 72, 82-91, 100, and 102, and 104 were pending in this application when last examined.

Claims 20, 25, 72, 84, and 89 have been withdrawn from consideration.

Claims 69, 70, 82, 83, 85-88, 90, 91, and 102 and 104 have been examined on the merits and stand rejected. No claims have been allowed.

In the interviews, Examiner Swope suggested that one option for expediting prosecution towards allowance was to change the invention from a method to a product directed to the polypeptide of SEQ ID NOS: 18. Examiner Swope graciously suggested this amendment and noted that such a shift to a different invention would be permitted in the instant application, upon the filing of an RCE. It was

noted that the sequences for SEQ ID NOS appear to be free of the prior art, but a further prior art search would have to be conducted by the Examiner. Kindly note that Applicants have been amended the claims in the manner suggested by the Examiner. Applicants again thank Examiner Swope her assistance in this application.

In particular, method claims 20, 25, 69, 70, 72, 82-91, 100, and 102, and 104 have been cancelled without prejudice or disclaimer thereto and replaced with new product claims 106-111, that are directed to varying scope of SEQ ID NOS: 18 and 19. Applicants reserve the right to file a continuation or divisional on any cancelled subject matter. As discussed in the most recent interview, the inclusion of SEQ ID NO: 18 (residues 640 to 720) and SEQ ID NO: 19 (residues 624 to 947) should be permissible and examined together, since SEQ ID NO: 18 is fully encompassed within SEQ ID NO: 19. In the event that the Examiner deems that only SEQ ID NO: 18, and not SEQ ID NO: 19, should be examined at this time, then Applicants would consider cancelling the claims to SEQ ID NO: 19 and proceeding with those to SEQ ID NO: 18.

Accordingly, new claim 106 is directed to SEQ ID NO: 19 and is written in "comprising" format and includes the variant, fragment, and derivative language corresponding

to that in previous claims 69 and 102. New claim 107 corresponds to claim 106 but is written in "consisting" format. New claim 108 is directed to SEQ ID NO: 18 and is written in "consisting" format and includes the same variant, fragment, and derivative language. New claims 109 and 110 depend on claim 106 and further specify the specific SED ID NOS: 18 and 19. Support for SEQ ID NOS: 18 and 19 can be found throughout the disclosure. See for example, 20, lines 9-10, page 21, lines 3-9, page 25, lines 25-26. New claim 111 further specifies a specific variant of claim 106, in which the codon corresponding to 860 of human NIK encodes arginine instead of glycine, as supported by the disclosure at page 21, lines 3-9 and page 53, lines 15-21. Thus, no new matter has been added.

Applicants wish to note that the polypeptide claims to SEQ ID NOS: 18 and 19 have been accepted in the corresponding EP application (EP 03 74 6399.9).

Claims 106-111 are pending upon entry of this amendment and these claims define patentable subject matter warranting their allowance for the reasons discussed herein.

II. Enablement and Written Description Rejections

In the Official Action, the examiner maintained the enablement rejection and the written description

rejection, despite the amendments and arguments in the response filed September 21, 2009.

In particular, claims 69, 70, 82, 83, 85-88, 90, 91, 102, 104, and 105 remain rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement for the reasons set forth on pages 2-4 of the Action.

Claims 69, 70, 82, 83, 85-88, 90, 91, 102, 104, and 105 also remain rejected under 35 U.S.C. § 112, first paragraph, for lack of written description support for the reasons set forth on page 4 of the Official Action.

These rejections are respectfully traversed for the reasons set forth in the last response (which arguments are reiterated herein by reference).

In the interview, Examiner Swope clarified and confirmed her positions with respect to the rejections. For the sole purpose of expediting prosecution and not to acquiesce to the rejections, the rejected claims have been cancelled, without prejudice or disclaimer, and replaced with new product claims 106-111, that are directed to SEQ ID NOS: 18 and 19.

In the interview, Examiner Swope indicated that the specification shows the following:

> (i) the C-terminal fragment of NIK, residues 624-947 (SEQ ID NO: 19) binds cγc in a yeast two hybrid assay (Ex. 1) (page 43, line 17 to page 44, line 21);

(ii) the C-terminal fragment of NIK, residues 624-947 (SEQ ID NO: 19) co-immunoprecipitates with cγc from transfected cells (Fig 2) (Ex. 2, page 45, lines 6-28);

(iii) the C-terminal fragment of NIK, residues 624-947 (SEQ ID NO: 19) inhibits binding between full-length NIK and full-length cγc (e.g., Table 1, page 45), and

(iv) the C-terminal fragment of NIK, residues 624-947 (SEQ ID NO: 19) inhibits NIK+cγc-induced and NIK-induced NFkB activation (Fig 5; and

(v) SEQ ID NO: 18, residues 640-720, also binds to cγc (Table 4).

Applicants respectfully submit that all of this supports the new product claims directed to the polypeptides of SEQ ID NOS: 18 and 19.

Further, as to SEQ ID NO: 18, residues 640-720, Applicants point to Table 4 on page 57 as evidence that this sequence binds to cγc (Table 4). This Table shows that the cγc binding region in NIK resides in 196 amino acids at the C-terminus of SEQ ID NO: 19, which in turn corresponds to residues 640-720 (SEQ ID NO: 18). Also, the specification discloses that the C-terminal fragment of NIK1 (consisting of SEQ ID NO: 18) binds a cγc in the yeast two-hybrid system and that a NIK1 and a cγc are co-immunoprecipitated from cells over-expressing these proteins (Examples 1-2). See also Example 7 (on page 57), which shows the binding of a

NIK C-terminus peptide (NIK624-947) (SEQ ID NO: 19) is '++++' with full-length common gamma chain. The specification, at page 20, lines 9-10, also clearly discloses that the NIK624-947 (SEQ ID NO: 19) comprises the claimed peptide, SEQ ID NO: 18 (NIK640-720), and that the latter peptide contains the important cγc binding domain of NIK. Since the claimed peptide of SEQ ID NO: 18 (NIK640-720) contains the important cγc binding domain of NIK624-947 (SEQ ID NO: 19), then it stands to reason that it too binds to cγc in the same manner as NIK624-947.

Again, it is respectfully submitted that the above-noted disclosure clearly supports and enables the new product claims directed to the polypeptides of SEQ ID NOS: 18 and 19. Thus, the present amendment obviates the current enablement and written description rejections. Withdrawal of the rejections is requested.

III. Conclusion

Applicant believes that all issues raised in the Official Action have been fully addressed in a manner that should lead to patentability of the present application. Favorable consideration and allowance are requested.

Applicants again thank Examiner Swope for her time and effort in the interviews with the undersigned. If the Examiner has any comments or proposals for expediting

prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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